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EXAMINER

CEGIELNIK, URSZULA M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 6, 8, 13, 19-21, and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbert (US Patent No. 6,961,622) in view of North et al. (US Patent No. 7,142,923) and Liss et al. (US Patent No. 5,851,223)

Gilbert discloses a housing (col. 6, line 12) conformable to a portion of a body, said housing being formed by one or more layers of water resistant material (the layers are substantially water resistant being made of polyethylene (which is thermoplastic) foam and protecting circuitry to a degree); a control circuit connected directly to two or more electrodes wherein said control circuit and said electrodes are substantially contained within the housing (col. 5, lines 60-67 through col. 6, lines 1-4); and a layer of electrical insulation surrounding at least a portion of the control circuit; a body; and wherein said apparatus is attachable to said body with adhesive comprising one or more electrogel pads; voltage intensity control; a battery (46); hydrogel; display indicating status and intensity.

Gilbert does not explicitly disclose a microprocessor having programmable intensities according to duty cycles; the duty cycles having the claimed ranges; the

Art Unit: 3711

polymeric material of the housing being polyvinyl chloride; the apparatus outputting a square waveform at a constant current.

North et al. teaches a neurostimulator that has a microprocessor that may be programmed to include different intensities with duty cycles.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a microprocessor as taught by North et al., since such a modification would permit specific intensity values with respect to a duty cycle to be given.

Liss et al. teach an apparatus outputs a plurality of electrical pulses, the plurality of electrical pulses including a first electrical pulse substantially larger than a plurality of subsequent substantially square waveform pulses (col. 10, lines 47-63 and Figures 1A-1D, 1F, and 1G – i.e. the prior art describes how to pick the proper amplitude [intensity] for the pulses. They increase the intensity until a specific reaction is achieved, then they back off on the intensity [lowering it] for the rest of the treatment); a square waveform at a constant current (see Figure 1C, for example).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a square wave at a constant current as taught by Liss et al., since such a modification would permit the timing of the control circuitry.

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a plurality of electrical pulses including a first electrical pulse substantially larger than a plurality of subsequent substantially

Art Unit: 3711

square waveform pulses, since such a modification would permit the desired treatment option in conjunction with the management of electrical impulses.

With regard to the number of intensities having a duty cycle, North et al. teaches a plurality of programs that each include a duty cycle. Because of the programmable capability of the microprocessor, it would logically follow that a third program with a corresponding duty cycle may be provided.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the number of intensities with a corresponding duty cycle being three as taught by North et al., since such modification would enhance the functionality of the device.

With regard to the claimed duty cycles each having a claimed range (value), North et al. teach programming the microprocessor to provide specific values of duty cycles in order to carry out programmed treatment.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide duty cycles with a range of values as taught by North et al., since such a modification would permit programmed treatment to be carried out.

With regard to the claimed duty cycles each having a claimed range (value), it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide first, second, third duty cycles with ranges 9 and 14%, 26 and 31%, and 47 and 53% (values of 45 milliseconds and 93 milliseconds), respectively, since it has been held that where the general conditions of a claim are disclosed in the

Art Unit: 3711

prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to the polymer housing being polyvinyl chloride, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the housing made of polyvinyl chloride, since the examiner takes Official Notice of the equivalence of polyvinyl chloride and polyethylene for their use in the foam art and the selection of any of these shown equivalents to provide a foam housing would be within the level of ordinary skill in the art.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Silverstone (US Patent No. 6,351,674).

The modified invention of Gilbert lacks an adjustable voltage intensity ranging from 90 to 180 volts.

Silverstone teaches an electrical stimulation device with voltages in the range between 90 and 180 volts (col. 3, lines 19-20).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed features as taught by Silverstone, since Silverstone states at col. 3, lines 19-20, that such voltages are known of typical stimulators.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Thomas (US Patent No. 5,107,835).

The modified invention of Gilbert lacks the apparatus using a frequency of approximately 0.1 to 4000 Hertz.

Thomas teaches an apparatus using a frequency of approximately 0.1 to 4000 Hertz (col. 2, lines 19-25).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Thomas, since Thomas states at col. 2, lines 19-20 that such a modification would decrease inflammation in an afflicted region in a patient.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of DiLorenzo (US Patent Application Publication No. 2003/0018367).

The modified invention of Gilbert lacks the apparatus having a pulse width of approximately 45 milliseconds and a range from .01 microsecond to 50 milliseconds.

DiLorenzo teaches an apparatus having a pulse width in the range of 1 microsecond and 1000 milliseconds (paragraph 0100, lines 8-10).

With regards to providing a pulse width from the range of .01 microsecond, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a pulse width from the range of .01 microsecond, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 333.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 above, and further in view of Zilber (US Patent No. 3,822,708),

The modified invention of Gilbert lacks the apparatus outputting approximately thirty pulses over a four-second duration.

Zilber teaches an apparatus outputting 5 to 200 pulses per second (col. 4, line 9).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the abovementioned claimed feature as taught by Zilber, since such a modification would permit a certain value of current to be passed.

With regards to providing the time period being four seconds, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a time period being four seconds, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 333.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urszula M. Cegielnik whose telephone number is 571-272-4420. The examiner can normally be reached on Monday through Friday, from 5:45AM-2:15PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eugene L. Kim can be reached on 571-272-4463. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3711

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/umc/

/Gene Kim/

Supervisory Patent Examiner, Art Unit 3711